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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

RIN 0920-AA38

[Docket No. CDC-2012-0009; NIOSH-258]

**Open-Circuit Self-Contained Breathing Apparatus Remaining
Service-Life Indicator Performance Requirements**

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: As a component of its ongoing update of respirator certification standards under Part 84 and in response to a petition to amend 42 CFR 84.83(f), HHS proposes a revision to the current requirement for open-circuit self-contained breathing apparatus (OC-SCBA) remaining service-life indicators (indicators), which are devices built into a respirator to alert the user that the breathing air provided by the respirator is close to depletion. HHS intends to revise the current standard, employed by the National Institute for Occupational Safety and Health (NIOSH) located within the Centers for Disease Control and Prevention (CDC), to allow greater latitude in the setting

of the indicator alarm to ensure that the alarm more effectively meets the different worker protection needs of different work operations. This revision sets a default service life at 25 percent of the rated service time and allows the indicator to be adjusted higher by the manufacturer, at the request of the purchaser.

DATES: Comments must be received by [INSERT 60 DAYS FOLLOWING PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by HHS RIN 0920-AA38, by either of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>.
Follow the instructions for submitting comments to Docket CDC-2012-0009.
- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MSC34, 4676 Columbia Parkway, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the

rulemaking process, see the "Public Participation" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or <http://www.cdc.gov/niosh/docket/review/docket258/default.html>.

FOR FURTHER INFORMATION CONTACT: Jonathan Szalajda, NIOSH
National Personal Protective Technology Laboratory (NPPTL), P.O.
Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236, (412)
386-5200 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

The preamble to this notice of proposed rulemaking is organized as follows:

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- I. Executive Order 13211 (Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use)
- J. Plain Writing Act of 2010
- V. Proposed Rule

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this proposal. In addition, HHS invites comment specifically on the following question related to this rulemaking:

1. HHS proposes that the remaining service-life indicator (indicator) be set at 25 percent of the rated service time of the respirator, as a default setting, with the option for the setting to be adjusted higher by the manufacturer, at the discretion of the purchaser. Is 25 percent of the rated service time of the respirator an appropriate default setting for the indicator?

2. Should the rule specify an upper limit that would require that the indicator be set to alarm no earlier than a set amount, such as 50 percent of rated service time? Are there possible emergency or rescue scenarios for which one would want an indicator to alarm at 50 percent or more of the rated service time?

Comments submitted should be titled "Open-Circuit Self-Contained Breathing Apparatus Remaining Service-Life Indicator Performance Requirements, RIN 0920-AA38," and should identify the author(s), return address, and a phone number, in case clarification is needed. Electronic comments can be submitted to <http://www.regulations.gov>. Printed comments can be sent to the NIOSH Docket Office at the address above. All communications received on or before the closing date for comments will be fully considered by HHS.

All relevant comments submitted will be available for examination in the rule docket (a publicly available repository of the documents associated with the rulemaking). A complete electronic docket containing all comments submitted will be available at <http://www.regulations.gov>; comments will be available in writing by request. All comments received are included without change in the dockets, including any personal information provided.

II. Background

A. Introduction

Under 42 CFR Part 84, "Approval of Respiratory Protective Devices" (Part 84), NIOSH approves respirators used by workers in mines and other workplaces for protection against hazardous

atmospheres. The Mine Safety and Health Administration (MSHA) and the Occupational Safety and Health Administration (OSHA) require U.S. employers to supply NIOSH-approved respirators to their employees whenever the employer requires the use of a respirator.

B. Background and Significance

Employers rely on NIOSH-approved respirators to protect their employees from airborne toxic contaminants and oxygen-deficient environments. More than 3.3 million private sector employees in the United States wear respirators for certain work tasks. The most effective and reliable means of protecting workers from oxygen-deficient environments is to prevent their causes or entry into them by workers. However, it is not technologically or economically feasible in all workplaces and operations to reduce airborne concentrations of contaminants to safe levels and to prevent exposure to oxygen-deficient environments. In such cases, workers depend on respirators to protect them from asphyxiation or airborne contaminants that are known or suspected to cause acute and chronic health effects, such as heavy metal poisoning, acid burns, chronic obstructive pulmonary disease, silicosis, neurological disorders, and cancer.

Open-circuit self-contained breathing apparatus are used

primarily by firefighters and other rescue workers to provide breathable air in an environment that may be immediately dangerous to life and health (IDLH). These respirators are characterized by a cylinder of compressed breathing air, which is inhaled by the user and then exhaled out of the system. OC-SCBA are required by HHS regulations to have a "remaining service life indicator or warning device,"¹ which is intended to alert users when the breathing air supply has been depleted to a certain percentage of breathing air available for use. The remaining service life indicator, referred to as a "low-air alarm," or "end-of-service-time indicator" by various industries, is relied upon by rescuers to warn when they have begun to utilize their reserve supply of breathing air. The current HHS regulation requires that the indicator alarms when the rated service time of the respirator is reduced to within 20 to 25 percent.

C. Need for Rulemaking

In 2003, NIOSH received a petition from David Bernzweig of the Columbus (OH) Professional Firefighters International Association of Fire Fighters Local 67 requesting that the agency initiate rulemaking to change the provisions of paragraph

¹ 42 CFR 84.71(a)(6).

§84.83(f).² The current rule requires that the indicator alarm within the 20 to 25 percent range; stakeholders request that HHS eliminate the lower value (20 percent) and require the indicator to alarm no later than at 25 percent of rated service time. NIOSH considered the request and facilitated discussion among stakeholders (see Section II.D. below). The National Fire Protection Association (NFPA), which sets standards for personal protective equipment used in the fire service, initiated an effort in 2008 to develop consensus on the matter and recently decided to propose amending NFPA 1981: Standard on Open-Circuit Self-Contained Breathing Apparatus (SCBA) for Emergency Services³ to require that the indicator alarm at 33 percent in its upcoming revision of the standard.

Studies conducted by NFPA have demonstrated that, while the number of structure fires in the United States has declined more than 50 percent between 1977 and 2002, the rate of traumatic firefighter deaths has increased in recent years.⁴ A majority of those deaths (over 63 percent) are due to smoke inhalation or asphyxiation, and many are attributed to firefighters going deep

² National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, transcript of public meeting held December 2, 2008. Available at <http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-034-A/0034-A-120208-Transcript.pdf>. Last accessed October 25, 2011.

³ NFPA 1981: Standard on open-circuit self-contained breathing apparatus (SCBA) for emergency services, Chapter 4. 2007 Edition.

⁴ National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, transcript of public meeting held December 2, 2008. Available at <http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-034-A/0034-A-120208-Transcript.pdf>. Last accessed October 25, 2011.

Fahy F. U.S. Fire Service fatalities in structure fires, 1977-2009. National Fire Protection Association. June 2010.

into large structures, becoming caught, lost, or disoriented, and then subsequently running out of breathing air before being able to exit.⁵ NFPA 1404, Standard for Fire Service Respiratory Protection Training, requires that firefighters leave the IDLH atmosphere before the indicator alarms, that is, before the individual begins to consume the respirator's reserve breathing air supply. While modern practice is for firefighters to practice "air management," or allocate enough breathing air for entry, work, and exit,⁶ many find maintaining situational awareness difficult.⁷ Many still rely on the indicator alarm to tell them to begin their exit, which is problematic because fire departments are finding that allotting 20-25 percent of the breathing air supply to exit does not allow enough time for escape from a large structure.⁸ If the firefighter becomes disoriented in the smoke, rescuers will have very little time to bring the individual out of the building unharmed.

OC-SCBA used in firefighting are certified by both NIOSH (under 42 CFR Part 84) and NFPA, under NFPA 1981: Standard on Open-Circuit Self-Contained Breathing Apparatus (SCBA) for

⁵ Fahy F. U.S. Fire Service fatalities in structure fires, 1977-2009. National Fire Protection Association. June 2010.

⁶ Bernocco S, Gagliano M, Phillips C, Jose P. Is your department complying with the NFPA 1404 air management policy? Fire Engineering 2008;161.

⁷ E.g. see, City of Charleston, Post incident assessment and review team. Firefighter fatality investigative report: Sofa Super Store, 1807 Savannah Highway, Charleston, SC, June 18, 2007. Phase II Report. May 15, 2008.

⁸ Marino D. Air management: Know your air-consumption rate. Fire Engineering. October 1, 2006.

Emergency Services.⁹ NFPA is proposing to increase the indicator alarm time in the 2013 edition of NFPA 1981 in order to provide the user with more reserve breathing air for self- or assisted-escape from the IDLH environment. Current NFPA standards require that the indicator "meet the activation requirements of NIOSH certification,"¹⁰ which may result in indicator notification at less than 25 percent of cylinder volume. As discussed above, this may not allow an early enough warning that the user has begun depleting the respirator's reserve breathing air. The NFPA has decided to amend its standard to increase the indicator setting to 33 percent (+5/-0).¹¹

HHS finds that revising §84.83(f) to allow greater latitude with regard to setting the indicator alarm would not reduce the amount of protection afforded to firefighters and other OC-SCBA users. In fact, HHS believes that specifying a default setting of 25 percent and allowing respiratory protection program managers to request the indicator to be set at a certain value will result in a more meaningful alarm that will reduce firefighter fatalities and may offer greater protection for users in other industries.

⁹ NFPA 1981: Standard on open-circuit self-contained breathing apparatus (SCBA) for emergency services, Chapter 4. 2007 Edition.

¹⁰ NFPA 1981: 6.2.3 (2007).

¹¹ Fahy RF, Fire Analysis and Research Division, National Fire Protection Association. "U.S. Fire Service fatalities in structure fires, 1977-2009." June 2010.

D. Public Meetings for Discussion and Comment

NIOSH held a public meeting to discuss underlying issues and technical matters addressed in this proposed rule on December 2, 2008, at the Pittsburgh Hyatt Regency, Pittsburgh International Airport (73 FR 65860, November 5, 2008). The official transcript of this meeting as well as public comments are available on NIOSH Docket 34-A (See <http://www.cdc.gov/niosh/docket/archive/docket034A.html>). NIOSH had previously collected public comments on remaining service-life indicators in 2004 (See NIOSH Docket 34, <http://www.cdc.gov/niosh/docket/archive/docket034.html>). Most comments were generally supportive of the need to modify the indicator requirement. Those opposed to changing the requirement generally recommended that efforts to improve training in air management techniques should be pursued instead of changing this indicator requirement.

III. Summary of Proposed Rule

This proposed change would establish a default setting of 25 percent, and allow purchasers to request that the manufacturer set the remaining service-life indicator alarm at a value appropriate for the purchaser's occupational needs. Although it is not required, purchasers may also have the indicator setting

modified for already fielded OC-SCBA units by an authorized representative of the manufacturer. The amendment would also codify a long-standing NIOSH policy requiring the indicator to alarm continuously until the respirator's breathing air supply is depleted.

HHS recognizes that not all OC-SCBA users find that the current standard places workers in jeopardy. Accordingly, HHS finds it prudent to retain the higher value (25 percent) established by the current regulation as a default setting, which would allow respiratory protection program managers who would prefer not to make any changes to the OC-SCBA used in their occupational setting to maintain their status quo. The proposed amendment to §84.83(f) would, however, allow managers who have determined that a higher set-point is warranted for their application the latitude to request a different value. Allowing managers to establish an earlier indicator alarm level would enable firefighters and incident commanders at structure fires involving substantial exit challenges to rely on the indicator alarm in emergency circumstances to warn that the reserve breathing air supply is being utilized. Allowing respiratory protection program managers to request that manufacturers set the indicator alarm at a certain value may also benefit workers in other industries that rely on OC-SCBA.

Alternatives Considered

While developing the proposed rule, HHS did not identify any acceptable alternatives to lifting the restriction created by the current regulation. We did, however, consider the appropriate value for the alarm, and the necessity for a single value or a range in which the alarm should sound. As discussed above, many OC-SCBA are used in occupational settings for which the current remaining service-life indicator setting of 25 percent has been integrated into user protocols without concern or incident. Different emergency and rescue uses are likely to be best served by different indicator alarm settings. For this reason, we did not find it appropriate to adopt the proposed NFPA standard, 33 percent, as the minimum alarm setting for all uses.

HHS also considered the possibility of allowing a "user-adjustable" alarm setting, but rejected that option because of the complexity of the remaining service-life indicator. Allowing respiratory program managers to adjust the settings in the field would require extensive training and due to the technical difficulties of this task would introduce a reliability (and hence safety) concern.

IV. Regulatory Assessment Requirements

A. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

This proposed rule is not being treated as a "significant" action under E.O. 12866. It would modify the settings for an indicator required by current regulation, as well as codify a long-standing policy of requiring that the indicator alarm continuously once it has begun. The current rule requires that a remaining service-life indicator alarm when the breathing air provided by an OC-SCBA reaches between 20 and 25 percent of its limit. The proposed rule would replace the range with a default value of 25 percent, which would allow facility managers to be able to request that the manufacturer set the indicator value at a higher limit than 25 percent of remaining breathing air. There are no costs and only benefits associated with this change: all approved OC-SCBA models have a remaining service-life indicator for which alarm limits are set during manufacturing; allowing respiratory protection program managers to specify that value (to be set by the manufacturer) if they find it necessary to do so will save lives by improving the respiratory protection of

emergency personnel and other users and indirectly by increasing the likelihood that victims will be successfully rescued in emergency response operations.

The rule does not interfere with State, local, or tribal governments in the exercise of their governmental functions.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., requires each agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations. As discussed above, all OC-SCBA models are equipped with a remaining service-life indicator that will not require any expenditure of resources to set at the proposed alarm limit. This proposed rule will allow small organizations such as local fire departments to specify their desired indicator limit when purchasing new devices from the manufacturer. The Secretary of HHS has certified to the Chief Counsel, Office of Advocacy of the Small Business Administration, that this rule does not have a significant impact on a substantial number of small entities. Accordingly, no regulatory impact analysis is required.

C. Paperwork Reduction Act of 1995

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq.,

requires an agency to invite public comment on and to obtain OMB approval of any regulation that requires 10 or more people to report information to the agency or to keep certain records. This rule does not contain any information collection requirements; thus HHS has determined that the PRA does not apply to this rule.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), HHS would report to Congress the promulgation of a final rule, once it is developed, prior to its taking effect. The report would state that HHS has concluded that the rule is not a "major rule" because it is not likely to result in an annual effect on the economy of \$100 million or more.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 et seq.) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this proposed rule does not include any Federal mandate that may

result in increased annual expenditures in excess of \$100 million by state, local or tribal governments in the aggregate, or by the private sector, adjusted annually for inflation. For 2011, the inflation-adjusted threshold is \$136 million.

F. Executive Order 12988 (Civil Justice)

This proposed rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform, and will not unduly burden the Federal court system. The proposed amendment to an existing respirator approval standard would apply uniformly to all applicants. This proposed rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The proposed rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this proposed rule on children. HHS has determined that the proposed rule would have no effect on children.

I. Executive Order 13211 (Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this proposed rule on energy supply, distribution, or use and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law No. 111-274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating the proposed rule consistent with the Federal Plain Writing Act guidelines.

V. Proposed Rule

List of Subjects in 42 CFR Part 84

Occupational safety and health, Personal protective

equipment, Respirators.

Text of the Rule

For the reasons discussed in the preamble, the Department of Health and Human Services proposes to amend 42 CFR Part 84 as follows:

PART 84--APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

1. The authority citation for Part 84 continues to read as follows:

Authority: 29 U.S.C. 577a, 651 *et seq.*, and 657(g); 30 U.S.C. 3, 5, 7, 811, 842(h), 844.

§ 84.83 [Amended]

2. Amend §84.83 as follows:

a. Revise paragraph (f) to read as follows:

§84.83 Timers; elapsed time indicators; remaining service life indicators; minimum requirements.

* * * * *

(f) Each remaining service-life indicator or warning device shall give an alarm when the reserve capacity of the apparatus is reached, and shall alarm continuously until depletion of the breathing air supply. The remaining service-life indicator shall be set by the manufacturer at 25 percent rated service time unless requested by purchasers to set the indicator to alarm at a higher value. For deployed units, the remaining service-life

indicator may be set by an authorized representative of the manufacturer.

Dated: June 11, 2012

Kathleen Sebelius
Secretary, Department of Health and Human Services

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